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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Safety Issues Pertaining to the Use of Flow Cytometry to Sort Human Cells for Clinical Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER), is announcing the following public meeting: "Safety Issues Pertaining to the Use of Flow Cytometry to Sort Human Cells for Clinical Applications." The public meeting is cosponsored by the International Society for Analytical Cytology (ISAC). The topics to be discussed are the scientific and technological issues related to developing voluntary safety protocols, which will be used to help ensure the safety of human cells that are sorted using flow cytometry for clinical applications.

Date and Time: The meeting will be held on April 20, 2001, from 9 a.m. to 5 p.m.

Location: The public meeting will be held at Bldg. 29, conference room 129 (9 a.m. to 12:30 p.m.) and Bldg. 29B conference rooms A and B (12:30 p.m. to 5 p.m.), National Institutes of Health, Bethesda, MD 20892.

Contact: Michele Keane-Moore, Center for Biologics Evaluation and Research (HFM–594), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–5102, FAX 301–827–5395, or e-mail to: keane-moore@cber.fda.gov.

Registration and Requests for Oral Presentations: Send or fax your registration information (including name, title, organization name, address, telephone, fax number, and e-mail address) and written material and requests to make oral presentations, to Michele Keane-Moore (address above) by Friday, April 13, 2001. There is no registration fee for the public meeting. Due to limited

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seating, interested parties are encouraged to register early. Registration at the site will be done on a space-available basis on the day of the workshop, beginning at 8 a.m.

If you need special accommodations due to a disability, contact Michele Keane-Moore at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The meeting on "Safety Issues Pertaining to the Use of Flow Cytometry to Sort Human Cells for Clinical Applications" will provide a forum for members of the public to discuss issues about maintaining the safety of cells prepared using flow cytometry.

The meeting is cosponsored by CBER and ISAC. The meeting will be of primary interest to public health professionals developing clinical protocols that use flow cytometry to sort human cells for readministration to patients and to manufacturers of these instruments. The objectives of the public meeting are to identify the safety issues related to using flow cytometry to sort populations of human cells and to establish a working group to formulate voluntary safety protocols that will help investigators ensure the safety and quality of cell-sorted products. The public meeting will specifically address: (1) The protection of flow cytometer operators from potential human pathogens, (2) the protection of the cellular product from contamination, (3) the cleaning and sterilization of the flow cytometer to help ensure a viable cellular product, and (4) other issues related to the development and adoption of these voluntary safety protocols.

Transcripts: Transcripts of the public meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the public meeting at a cost of 10 cents per page. The transcript will also be available on the Internet at http://www.fda.gov/cber/minutes/workshop-min.htm.

Dated: 4/3/01

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April 3, 2001.

William Hubbard

William K Hubbard,
Senior Associate Commissioner for Policy,
Planning, and Legislation.

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